REMARKS

Applicant affirms the election without traverse to the Invention of Group I, Claims 1-9, with gabapentin as the elected species. Claims 10-17 have thus been withdrawn from examination. Claims 1-9 have been amended. Claims 18-22 are new. The new claims are supported by the Specification as filed and thus do not constitute new matter. Claims 1-9 and 18-22 are thus currently pending in the present application.

Claim Objections

The Examiner objected to Claims 4-9 under 37 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and because of word mis-spellings. In response to the Examiner's objection, the claims have been amended so that the multiple dependencies are in proper form. Also, the term "butanic" has been replaced by the term "butanoic" in the claims as needed. As a result, Applicant submits that amended Claims 4-9 are in condition for examination and request allowance of the same.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected Claims 1-9 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner points out that in Claim 1, the Applicant recites a 4-amino-3-substituted-butanoic acid derivative of formula I, wherein R_1 and R_2 have various definitions. However, the compound of formula I accompanying Claim 1 does not contain any R groups. The Examiner is correct in postulating that the Applicant intended Claim 1 to recite a compound of formula I, as depicted by the structure on page 6, line 17, of the specification. Applicant has consequently amended Claim 1, by replacing the originally depicted structure with the structure disclosed on page 6, line 17, of the specification.

The Examiner also requested that the Applicant clarify whether the alpha amino acid is part of the R_2 substituent or is independently used as the stabilizer. The Applicant has amended

Claim 1 so that it is clear that the alpha amino acid is not part of the R_2 substituent and is independently used as the stabilizer.

In a related vein, the Examiner asked the Applicant to clarify the definition of the term "4-amino-3-substituted–butanoic acid derivative" (does it mean "4-amino-3-substituted–butanoic acid derivative" *alone* or in combination with the stabilizing amino acid?). Applicant has amended the claims reciting "4-amino-3-substituted–butanoic acid derivative" so that it is clear that this term exclusively refers to 4-amino-3-substituted–butanoic acid derivatives.

Applicant respectfully submits that as amended, Claims 1-9 comport with the requirements of 35 U.S.C. § 112, second paragraph, and request consideration and allowance of the same.

Rejections under 35 U.S.C. § 102

The Examiner rejected Claims 1-6 and 9 under 35 U.S.C. § 102 (b) as being anticipated by Woodruff (U.S. Patent No. 5,084,479). According to the Examiner, Woodruff teaches a composition comprising gabapentin and glycine (col. 7, line 11-12 and Table 3). This rejection is respectfully traversed.

The present invention is directed to a pharmaceutical composition or formulation comprising (a) an α amino acid; (b) an optional auxiliary agent for manufacturing a pharmaceutical preparation; and (c) a 4-amino-3-substituted-butanoic acid derivative. As a preliminary matter, pharmaceutical compositions containing a 4-amino-3-substituted-butanoic acid derivative may be used to treat various cerebral diseases (p. 2, lns. 1-21). However, preparing a pharmaceutical formulation containing a 4-amino-3-substituted-butanoic acid derivative, may be problematic. The 4-amino-3-substituted-butanoic acid derivative known as gabapentin, has poor aqueous stability and undergoes autodegradation (p. 3, lns. 7-15). Thus, the present invention discloses a formulation that does not degrade.

In contrast to the present invention, Woodruff discloses a method for treating neurodegenerative diseases using cyclic amino acids, not pharmaceutical formulations. Therefore, a first analysis clearly indicates that Woodruff fails to anticipate the present invention.

In addition, on a more particular level, Applicants emphasize that *Woodruff does not teach a composition comprising gabapentin and glycine.* Woodruff discloses several injectable solutions that were used in whole-cell patch clamp experiments (col. 5, line 66). Woodruff employed these experiments to investigate the effects of the anitepileptic drug, gabapentin, upon the responses of striatal neurons in dissociated culture to NMDA (col. 5, line 66 through col. 6, line 2). The Woodruff disclosure identifies three discrete injectable solutions:

I. The *first and second solutions* were prepared from a drug and an extracellular solution (col. 6, lines 45-46). The drugs were dissolved to a known concentration and are applied via the perfusion system (col. 6, lines 46-47). For example, 10 μM solutions each of gabapentin (col. 6, line 65) and strychnine (col. 7, line 12) were prepared.

II. The *third solution* was prepared from glycine and the extracellualr solution at a concentration of 10-100 μM (col. 6, line 52).

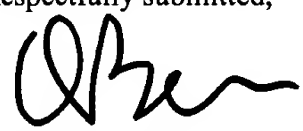
Woodruff discloses that the injectable solutions of gabapentin, glycine, and strychnine, were *concurrently applied* (col. 7, lines 11-12). However, Woodruff does not disclose *a solution*, let alone *a composition* comprising gabapentin and glycine. This assertion is supported by Figure 3A-B of Woodruff. Figure 3A-B shows voltage clamp records from a 14 day-old striatal neuron held at a holding potential of –70 mV (col. 4, lines 57-59). In the Figure, inverted triangles indicate periods of rapid pressure ejection of NMDA via the perfusion system (col. 6, lines 59-60). Solid bars indicate periods of drug application via the perfusion system (col. 6, lines 60-61). In Figure 3B, a copy of which is attached herewith, there are four signals. In the third signal from the left, there are two solid bars, indicating the injection of (1) 1 μM glycine and 10 μM strychnine and (2) 10 μM gabapentin. Thus, Figure

3B qualifies as proof that Woodruff does not disclose a gabapentin-glycine composition. As a result, Applicant respectfully submits that Claims 1-6 and 9 comport with the requirements of 35 U.S.C. § 102(b) and are not anticipated by Woodruff.

The Examiner also rejected Claims 1-9 under 35 U.S.C. § 102 (b) as being anticipated by Robson (U.S. Patent No. 4,126,684). Robson discloses a pharmaceutical composition comprising (a) an effective amount of an addicting agent, (b) an effective amount of a 4-amino-3-p-halophenyl-butyric acid, and (c) a pharmaceutical excipient (lns. 36-43). The disclosed purpose of the Robson invention is to prevent future addiction or to ameliorate the withdrawal symptoms in the addicted by using a combination of an addicting agent with a 4-amino-3-p-halophenyl-butyric acid (col. 1, lns. 29-33). Each of the examples disclosed by Robson discloses such a combination (see Examples 1 and 2). As a result, Applicants contend that Robson does not anticipate the present invention.

The Examiner is invited to contact the Applicant's attorney at the telephone number provided below to discuss any questions or aspects of the present case.

Respectfully submitted,



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Attachment - Amendments, Version with Markings to Show Changes Made; Figs. 3A and #B of U.S. Pat. No. 5,084,479

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

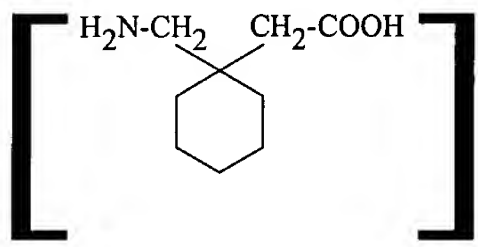
IN THE SPECIFICATION:

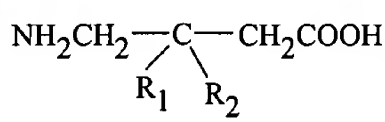
Table 4

Storage Conditions	Samples		
	(d)	[(3)] (e)	(f)
When initiated	0.008	0.008	0.008
45°C/1 week (sealed)	0.253	0.311	0.178
45°C/2 weeks (sealed)	0.543	0.616	0.375
45°C/3 weeks (sealed)	0.846	0.947	0.570

IN THE CLAIMS:

1. (AMENDED). A stabilized pharmaceutical preparation [containing a 4-amino-3-substituted-butanoic acid derivative which comprises a 4-amino-3-substituted- butanoic acid derivative having the general formula], comprising: (a) an α amino acid; (b) an optional auxiliary agent for manufacturing a pharmaceutical preparation; and (c) a 4-amino-3-substituted-butanoic acid derivative, which 4-amino-3-substituted-butanoic acid derivative has the general formula:





wherein,

R_1 is a hydrogen atom, a hydroxyl group, a methyl group or an ethyl group;

R_2 is a monovalent group selected from:

a straight or branched alkyl group of 3 - 8 carbon atoms;

a straight or branched alkylene group of 3 - 8 carbon atoms;

a straight or branched alkyl group of 3 - 8 carbon atoms which is mono- or di-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a cycloalkyl group of 3 - 8 carbon atoms;

a cycloalkyl group of 3 - 8 carbon atoms which is mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkyl group of 4 - 8 carbon atoms;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkyl group of 4 - 8 carbon atoms wherein said phenyl ring is mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkenyl group of 5 - 8 carbon atoms or a cycloalkanedienyl group of 5 - 8 carbon atoms;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkenyl group of 5 - 8 carbon atoms or a cycloalkanedienyl group of 5 - 8 carbon atoms wherein said phenyl ring is mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group;

an alkylcycloalkyl group wherein said cycloalkyl has 3 - 8 carbon atoms and is linked to an alkylene group having 1 - 4 carbon atoms optionally interrupted with -O-, -S- or -SS-;

an alkylcycloalkyl group wherein said cycloalkyl has 3 - 8 carbon atoms, is linked to an alkylene group having 1 - 4 carbon atoms optionally interrupted with -O-, -S- or -SS- and is mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a cycloalkyl group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) is replaced by -O-, -NH-, -S-, -SO- or $-S(O)_2-$;

a cycloalkyl group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) is replaced by -O-, -NH-, -S-, -SO- or $-S(O)_2-$, and one or two of the unsubstituted methylene groups ($-CH_2-$) are mono- or di-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a cycloalkenyl group of 5 - 8 carbon atoms or a cycloalkanedienyl group of 5 - 8 carbon atoms, one of the methylene groups ($-CH_2-$) in said cycloalkenyl ring or cycloalkanedienyl ring being replaced by -O-, -NH-, =N-, -S-, -SO- or $-S(O)_2-$;

a cycloalkenyl group of 5 - 8 carbon atoms or a cycloalkanedienyl group of 5 - 8 carbon atoms, one of the methylene groups ($-CH_2-$) in said cycloalkenyl ring or cycloalkanedienyl ring being replaced by -O-, -NH-, =N-, -S-, -SO- or $-S(O)_2-$, and one or two of the unsubstituted methylene groups ($-CH_2-$) being mono- or di-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkyl group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) is replaced by -O-, -NH-, -S-, -SO- or $-S(O)_2-$;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkyl group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) is replaced by -O-, -NH-, -S-, -SO- or $-S(O)_2-$, said phenyl group being mono- or di-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkenyl group of 5 - 8 carbon atoms or a cycloalkanedienyl group of 5 - 8 carbon atoms, one of the methylene groups ($-CH_2-$) in said cycloalkenyl ring or cycloalkanedienyl ring being replaced by -O-, -NH-, =N-, -S-, -SO- or $-S(O)_2-$;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkenyl group of 5 - 8 carbon atoms or a cycloalkanedienyl group of 5 - 8 carbon atoms, one of the methylene groups ($-CH_2-$) in said cycloalkenyl ring or cycloalkanedienyl ring being replaced by -O-, -NH-, =N-, -S-, -SO- or -S(O)2-, said phenyl ring being mono- or di-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group;

an alkylcycloalkyl group wherein said cycloalkyl has 5 - 8 carbon atoms and is linked to an alkylene group having 1 - 4 carbon atoms optionally interrupted with -O-, -S- or -SS-, one of the methylene groups ($-CH_2-$) in said cycloalkyl ring being replaced by -O-, -NH-, -S-, -SO- or $-S(O)_2-$;

an alkylcycloalkyl group wherein said cycloalkyl has 5 - 8 carbon atoms and is linked to an alkylene group having 1 - 4 carbon atoms optionally interrupted with -O-, -S- or -SS-, and one of the methylene groups ($-CH_2-$) in

said cycloalkyl ring being replaced by -O-, -NH-, -S-, -SO- or -$S(O)_2$- and one or two of the unsubstituted methylene groups (-CH_2-) being mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a phenyl or naphthyl group;

a phenyl group substituted with a methylenedioxy group;

a phenyl or naphthyl group which is mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an amino group, a nitro group, a carboxyl group, a phenoxy group, a phenylmethoxy group, a phenylmethoxy group wherein said phenyl ring is mono-substituted with a halogen atom, trifluoromethyl group, an alkoxy group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group, a cycloalkylmethoxy group having 5 - 8 carbon atoms in the cycloalkyl ring, a cycloalkenylmethoxy group having 5 - 8 carbon atoms in the cycloalkenyl ring, a cycloalkanedienylmethoxy group having 5 - 8 carbon atoms in the cycloalkanedienyl ring, a cycloalkylmethoxy group wherein one of the methylene groups (-CH_2-) in said cycloalkyl ring having 5 - 8 carbon atoms is replaced by -O-, -NH-, -S-, -SO- or -$S(O)_2$-, a cycloalkenylmethoxy group wherein one of the methylene groups (-CH_2-) in said cycloalkenyl ring having 5 - 8 carbon atoms is replaced by -O-, -NH-, =N-, -S-, -SO- or -$S(O)_2$-, a cycloalkanedienyl-methoxy group wherein one of the methylene groups (-CH_2-) in said cycloalkanedienyl ring having 5 - 8 carbon atoms is replaced by -O-, -NH-, =N-, -S-, -SO- or -$S(O)_2$- group, a cycloalkylmethoxy group having 5 - 8 carbon atoms in the cycloalkyl ring wherein said cycloalkyl ring is mono-substituted with a halogen atom, trifluoromethyl group, a hydroxy group, an alkyl group, an alkoxy group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group and one of the methylene groups (-CH_2-) in said cycloalkyl ring is replaced by -O-, -NH-, -S-, -SO- or -$S(O)_2$-, a

cycloalkenylmethoxy group having 5 - 8 carbon atoms in the cycloalkenyl ring wherein said cycloalkenyl ring is mono-substituted with a halogen atom, a trifluoromethyl group, a hydroxy group, an alkyl group, an alkoxy group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group and one of the methylene groups ($-CH_2-$) in said cycloalkenyl ring is replaced by -O-, -NH-, =N-, -S-, -SO- or $-S(O)_2-$, or a cycloalkanedienylmethoxy group having 5 - 8 carbon atoms in the cycloalkanedienyl ring wherein said cycloalkanedienyl ring is mono-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group and one of the methylene groups ($-CH_2-$) in said cycloalkanedienyl ring is replaced by -O-, -NH-, =N-, -S-, -SO- or $-S(O)_2-$;

an alkylphenyl group wherein said phenyl group is linked to an alkylene group having 1 - 4 carbon atoms optionally interrupted with -O-, -S- or -SS-;

an alkyl-O-, -S- or -SS-phenyl group wherein said phenyl group is linked to an alkylene group having 1 - 4 carbon atoms via -O-, -S- or -SS-;

an -O-, -S- or -SS-phenyl group;

a diphenylamino group;

an alkylphenyl group wherein said phenyl group is linked to an alkylene group having 1 - 4 carbon atoms optionally interrupted with -O-, -S- or -SS- and mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, a alkyl group, an alkoxy group, an amino group, a nitro group or a carboxyl group;

an alkyl-O-, -S- or -SS-phenyl group wherein said phenyl group is linked to an alkylene group having 1 - 4 carbon atoms via -O-, -S- or -SS- and mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an amino group, a nitro group or a carboxyl group;

an -O-, -S- or -SS-phenyl group wherein said phenyl group is mono-, di- or tri-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an amino group, a nitro group or a carboxyl group;

or

R_1 and R_2, together with the carbon atom to which they are attached, may form a divalent group selected from:

a cycloalkylidene group of 5 - 8 carbon atoms;

a cycloalkylidene group of 5 - 8 carbon atoms which is mono-, di-, tri- or tetra-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, a cycloalkyl group, a phenyl group, an amino group, a nitro group or a carboxyl group;

a cycloalkylidene group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) in said cycloalkyl ring is replaced by -O-, -NH-, -S-, -SO- or $-S(O)_2-$;

a cycloalkylidene group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) in said cycloalkyl ring is replaced by -O-, -NH-, -S-, -SO- or $-S(O)_2-$ group and one or more of the unsubstituted methylene groups ($-CH_2-$) in said cycloalkyl ring are mono-, di-, tri- or tetra-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a cycloalkenylidene group of 5 - 8 carbon atoms or a cycloalkanedienylidene group of 5 - 8 carbon atoms;

a cycloalkenylidene group of 5 - 8 carbon atoms or a cycloalkanedienylidene group of 5 - 8 carbon atoms which is mono-, di-, tri- or tetra-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, a cycloalkyl group, a

phenyl group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a cycloalkenylidene group of 5 - 8 carbon atoms or a cycloalkanedienylidene group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) in said cycloalkenyl ring or cycloalkanedienyl ring is replaced by -O-, -NH-, =N-, -S-, -SO- or $-S(O)_2-$;

a cycloalkenylidene group of 5 - 8 carbon atoms or a cycloalkanedienylidene group of 5 - 8 carbon atoms wherein one of the methylene groups ($-CH_2-$) in said cycloalkenyl ring or cycloalkanedienyl ring is replaced by -O-, -NH-, =N-, -S-, -SO- or $-S(O)_2-$ group and one or more of the unsubstituted methylene groups ($-CH_2-$) in said cycloalkenyl ring or cycloalkanedienyl ring are mono-, di-, tri- or tetra-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, an oxo group, a carboxyl group or a carboalkoxy group;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkylidene group of 4 - 8 carbon atoms;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkylidene group of 4 - 8 carbon atoms, said phenyl ring being mono-, di-, tri- or tetra-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an alkoxy group, an alkylthio group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group;

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkenylidene group of 5 - 8 carbon atoms or a cycloalkanedienylidene group of 5 - 8 carbon atoms; or

a condensed ring group formed by ortho-fusion of a phenyl ring with a cycloalkenylidene group of 5 - 8 carbon atoms or a cycloalkanedienylidene group of 5 - 8 carbon atoms, said phenyl ring being mono- or di-substituted with a halogen atom, a trifluoromethyl group, a hydroxyl group, an alkyl group, an

alkoxy group, an alkylthio group, an amino group, a nitro group, a carboxyl group or a carboalkoxy group; or

provided that when R_2 is a phenyl or naphthyl group which is mono-, di- or tri-substituted with a halogen atom, the α-amino acid is not glycine

[an α-amino acid; and, if necessary, an auxiliary agent for manufacturing a pharmaceutical preparation].

2. (AMENDED). The stabilized pharmaceutical preparation [containing the 4-amino-3-substituted-butanoic acid derivative as claimed in] of Claim 1 wherein said α-amino acid is one or more selected from

the L-, D- and DL-forms of neutral α-amino acids;

alkali salts, acid amides, alkyl-substituted derivatives of acid amides or alkyl esters of the L-, D- and DL-forms of acidic α-amino acids;

acid addition salts or monoacylated derivatives of the L-, D- and DL-forms of basic α-amino acids;

α,ω-diaminodicarboxylic acids; and

acidic amino acid-basic amino acid adducts of the L-, D- and DL-forms of acidic α-amino acids and the L-, D- and DL-forms of basic α-amino acids.

3. (AMENDED). The stabilized pharmaceutical preparation [containing the 4-amino-3-substituted-butanoic acid derivative as claimed in] of Claim 2 wherein said α-amino acid is one or more selected from

neutral α-amino acids consisting of glycine, phenylglycine, hydroxyphenylglycine, dihydroxyphenylglycine, L-alanine, hydroxy-L-alanine, L-leucine, hydroxy-L-leucine, dihydroxy-L-leucine, L-norleucine, methylene-L-norleucine, L-ketonorleucine, L-isoleucine, hydroxy-L-isoleucine, dihydroxy-L-isoleucine, L-valine, hydroxy-L-valine, L-isovaline, L-norvaline, hydroxy-L-norvaline,

hydroxy-L-ketonorvaline, L-methionine, L-homomethionine, L-ethionine, L-threonine, acetyl-L-threonine, L-tryptophan, hydroxy-L-tryptophan, methyl-L-tryptophan, L-tyrosine, hydroxy-L-tyrosine, methyl-L-tyrosine, bromo-L-tyrosine, dibromo-L-tyrosine, 3,5-diiodo-L-tyrosine, acetyl-L-tyrosine, chloro-L-tyrosine, L-m-tyrosine, L-levodopa, L-methyldopa, L-thyroxine, L-serine, acetyl-L-serine, L-homoserine, acetyl-L-homoserine, ethyl-L-homoserine, propyl-L-homoserine, butyl-L-homoserine, L-cystine, L-homocystine, methyl-L-cysteine, allyl-L-cysteine, propyl-L-cysteine, L-phenylalanine, dihydro-L-phenylalanine, hydroxymethyl-L-phenylalanine, L-aminobutyric acid, L-aminoisobutyric acid, L-ketoaminobutyric acid, dichloro-L-aminobutyric acid, dihydroxy-L-aminobutyric acid, phenyl-L-aminobutyric acid, L-aminovaleric acid, L-aminohydroxyvaleric acid, dihydroxy-L-aminovaleric acid, L-aminoisovaleric acid, L-aminohexanoic acid, methyl-L-aminohexanoic acid, L-aminoheptanoic acid, L-aminooctanoic acid and citrulline and the D- and DL-forms thereof;

acidic α-amino acids consisting of L-aspartic acid, L-glutamic acid, L-carbocysteine, L-aminoglutaric acid, L-aminosuccinic acid, L-aminoadipic acid, L-aminopimelic acid, hydroxy-L-aminopimelic acid, methyl-L-aspartic acid, hydroxy-L-aspartic acid, methyl-L-glutamic acid, methyl-hydroxy-L-glutamic acid, L-methyleneglutamic acid, hydroxy-L-glutamic acid, dihydroxy-L-glutamic acid and hydroxy-L-aminoadipic acid and the D- and DL-forms thereof;

basic α-amino acids consisting of L-arginine, L-lysine, L-ornithine, L-canavanine, L-canaline, hydroxy-L-lysine, L-homoarginine, hydroxy-L-homoarginine, hydroxy-L-ornithine, L-diaminopropionic acid, L-diaminohexanoic acid, L-diaminobutyric acid, L-diaminovaleric acid, L-diaminoheptanoic acid, and L-diaminooctanoic acid and the D- and DL-forms thereof; and

α,ω-diaminodicarboxylic acids consisting of diaminosuccinic acid, diaminoglutaric acid, diaminoadipic acid and diaminopimelic acid;

provided that, when said α-amino acid is an adipic α-amino acid, it is used in the form of the corresponding alkali salt, acid amide, alkyl-substituted derivative of acid amide or alkyl ester thereof, or

when said α-amino acid is a basic α-amino acid, it is used in the form of the corresponding acid addition salt or monoacylated derivative thereof, or

said acidic α-amino acid and said basic α-amino acid are also used in the form of the corresponding acidic amino acid-basic amino acid adduct.

4. (AMENDED). [The] A stabilized pharmaceutical preparation [containing a 4-amino-3-substituted-butanic acid derivative] as claimed in [any of] Claims [1-3] 1, 2, or 3 wherein a total amount of said α-amino acid is in the range of 0.001 - 80 moles per mole of the 4-amino-3-substituted-[butanic]butanoic acid derivative.

5. (AMENDED). [The] A stabilized pharmaceutical preparation [containing a 4-amino-3-substituted-butanic acid derivative] as claimed in [any of] Claims [1-4] 1, 2, 3, or 4 wherein it is in the form of liquid preparations.

6. (AMENDED). [The] A stabilized pharmaceutical preparation [containing a 4-amino-3-substituted-butanic acid derivative] as claimed in Claim 5 wherein it is in the dosage form of liquid preparations, syrups or injections.

7. (AMENDED). [The] A stabilized pharmaceutical preparation [containing a 4-amino-3-substituted-butanic acid derivative] as claimed in [any of] Claims [1-4] 1, 2, 3, or 4 wherein it is in the form of solid preparations.

8. (AMENDED). [The] A stabilized pharmaceutical preparation [containing a 4-amino-3-substituted-butanic acid derivative] as claimed in Claim 7 [wherein it] which is in the dosage form of tablets, powders, granules or capsules.

9. (AMENDED). [The] A stabilized pharmaceutical preparation [containing a 4-amino-3-substituted-butanic acid derivative] as claimed in [any of] Claims [1-8] 1, 2, 3, 4, 5, 6, 7, or 8 [wherein it] which is a gabapentin-containing preparation, a pregabalin-containing preparation, a baclofen-containing preparation, or a preparation containing 3-aminomethyl-4-cyclohexyl-butanoic acid, 3-aminomethyl-5-cyclohexyl-pentanoic acid, 3-aminomethyl-4-phenyl-butanoic acid or 3-aminomethyl-5-phenyl-pentanoic acid.

18. (NEW). A stabilized pharmaceutical preparation containing an α amino acid, an auxiliary agent for manufacturing a pharmaceutical preparation if necessary, and gabapentin.

19. (NEW). The stabilized pharmaceutical preparation of Claim 10 wherein the α amino acid is as provided in Claims 2 or 3.

20. (NEW). The stabilized pharmaceutical preparation containing of Claims 10 or 11 in the form of liquid preparations, syrups, or injections.

21. (NEW). The stabilized pharmaceutical preparation of Claims 10 or 11 in the form of solid preparations.

22. (NEW). The stabilized pharmaceutical preparation of Claim 13 in the dosage forms of tablets, powders, granules, or capsules.

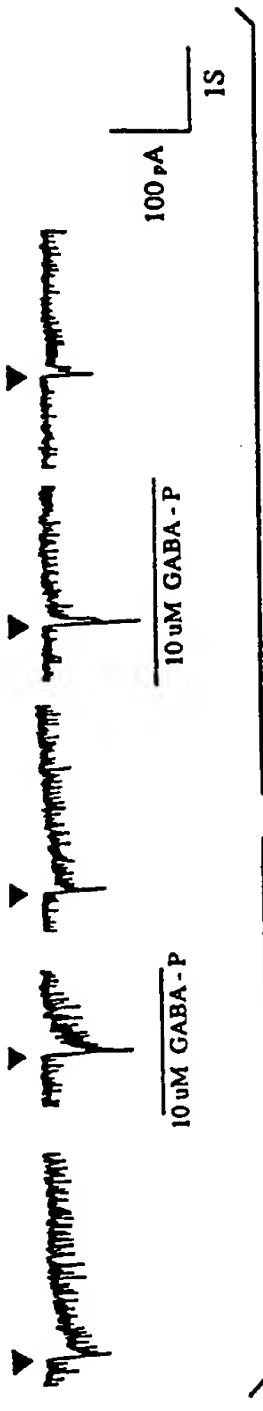

100 pA
1S
10 uM GABA-P
10 uM GABA-P

FIG. 3A

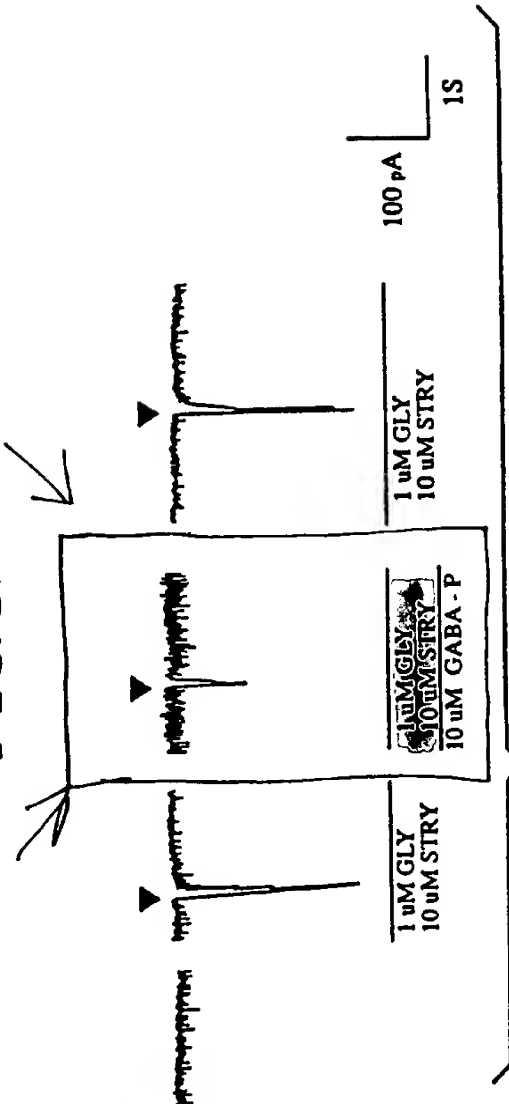

100 pA
1S
1 uM GLY
10 uM STRY
1uM GLY
10 uM STRY
10 uM GABA-P
1 uM GLY
10 uM STRY

FIG. 3B